

agent into normal heart tissue. The subject matter of the remaining restriction groups is drawn to the same methods but further specify that the therapeutic agent comprises a protein (Group II), a nucleic acid (Group III), an antisense molecule (Group IV) or cells (Group V).

In the Response, Applicant elected the subject matter of Group I for prosecution and acknowledged that a species election had been set forth for particular claims –none of which were (or are) are part of the elected group. Applicant did not intend to be non-responsive (or even partially non-responsive), but based upon past experience with restriction requirements which contain both group elections and species elections, believed it was proper and fully responsive to defer any species election within a non-elected groups until that subject matter of that group was prosecuted (typically in a divisional application). In this case, Applicant carefully reviewed the claims for which a species election was requested, determined that none were part of Group I and believed in good faith that no further election was necessary in the Response. Moreover, it was unclear whether one or four separate species elections were being required in view of the fact that none of the “species-containing” claims were elected.

In the requirement, the Examiner’s species election is based upon requiring

- (1) a species election for claims 5, 7, 25, 42 and 44, as generic to a plurality of species comprising FGF-1, FGF-2, FGF-5, VEGF, VEGF165, HIF-1, PDGF-1, PDGF-2, DEL1, angiopoietin, HGF, MCP-1, eNOS and iNOS;
- (2) a species election for claim 27, as generic to a plurality of species comprising FGF-5, acidic FGF, basic FGF, PDGF-1, PDGF-2, VEGF, an endothelial growth factor and a vascular smooth muscle growth factor;
- (3) a species election for claims 30 and 32, as generic to a plurality of species comprising cTNC, MHC alpha, MHC beta, MLC2v, NppA and CARP; and
- (4) a species election for claims 13 and 50, as generic to a plurality of species comprising endothelial progenitor cells, mononuclear cells, bone marrow stromal cells, stem cells, cardiac myoblasts and whole filtered bone marrow.

However, as indicated, and in order to be fully responsive to the Examiner's current request, Applicant reiterates its provisional election, with traverse, to prosecute the subject matter of Group I, Claims 1-3, 15, 17, 19, 21, 36-40 and 52-54, and further provisionally elects, with traverse, to prosecute the species of (1) VEGF for Claims 5, 7, 25, 42 and 44; (2) VEGF for Claim 27; (3) the cTNC promoter for Claims 30 and 32; and (4) stem cells for Claims 13 and 50. Applicant reserves the right to file a divisional application directed to the non-elected subject matter of this application.

While Applicant has responded as requested, nonetheless, having four separate species elections does not make sense when three of four species categories are subgeneric to the broader therapeutic agent and the last category does not at all relate to the therapeutic agent but rather relates to tissue-specific promoters for controlling gene expression in the heart --and again none of the claims with such species were elected for prosecution.

The present invention is based upon the surprising finding that a favorable functional response occurs when the therapeutic agent is injected into the normal myocardium, and more particularly into the normal myocardium adjacent to an ischemic zone. Hence the generic claims are sufficiently broad to embrace the method when used for delivery of a many different therapeutic agents, including where the therapeutic agent is a protein, a nucleic acid, an antisense molecule or cells. Given the presently claimed subject matter, Applicant does not believe that a species election changes the search burden upon the Examiner.

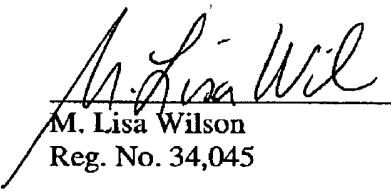
Finally, Applicant respectfully requests that the Examiner reconsider and withdraw the present species election in view of the added expense that Applicant must now incur despite having made a *bona fide* attempt to fully respond to the original Action on the belief that non-elected claims were withdrawn from consideration and that addressing matters pertaining to such

claims was deferrable. Moreover, 37 C.F.R. § 1.135(c), provides that new time period for reply may be set when an applicant's reply was a bona fide attempt to advance prosecution of the application and substantially complete but consideration of some matter or compliance with some requirement was inadvertently omitted. Accordingly, Applicant respectfully requests refund of the extension fee paid in the accompanying Petition for Extension Time.

If there are any issues outstanding after consideration of this species election, the Examiner is invited to contact the undersigned to expedite prosecution of this case.

Respectfully submitted,

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